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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,578	06/28/2007	Malcolm King	14628-2	1996

1059 7590 04/26/2011

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EXAMINER	
HOLT, ANDRIAE M	
ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
04/26/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,578	KING ET AL.	
	Examiner	Art Unit	
	ANDRIAE M. HOLT	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 14-16* is/are pending in the application.

4a) Of the above claim(s) *3. 5-6. and 10-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,7,8 and 14-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/4/2010; 4/6/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-12 and 14-16 are pending in the application.

Election/Restrictions

Applicant's election without traverse of Group II, claims 1-3, 7-9, and 14-16, in the reply filed on October 28, 2010 is acknowledged.

Applicant's election of species with traverse of mucus functions, epithelial protection, and mucus lining, respiratory system, in the reply filed on October 28, 2010 is acknowledged. The traversal is on the ground(s) that the examiner has not shown that it would be an undue burden to search the subject matter of all the listed species together. This is not found persuasive because as noted in the Election of Species issued September 30, 2010, the species lack the same or corresponding special technical features for the following reasons: Pursuant to PCT Rule 13.2 and PCT Administrative Instructions, Annex B, Part 1 (f)(l)(B)(2), the species are not art recognized equivalents. The mucous function of respiratory tract mucus clearing is very different from the mucus function of nutrient intake and would require a very different field of search, respiratory system versus digestive system. Likewise, the mucus lining of the respiratory system is very different from the lining of the digestive system or the reproductive system. The field of search for the respiratory system would include searching the lungs and nasal system which is different from the field of search for the digestive system which includes the stomach and intestines and the reproductive system, which would include the ovaries of female subjects.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-12 and 14-16 are pending in this application. Claims 3, 5-6, and 10-12 are withdrawn from consideration as being drawn to a non-elected invention and species. Claims 1-2, 4, 7-9, and 14-16 will presently be examined to the extent they read on the elected subject matter of record

Priority

This Application is a National Stage Entry for PCT/CA05/00463 filed on March 30, 2005. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) is acknowledged. Benefit of US Provisional Application No. 60/557,402 filed March 30, 2004 is acknowledged.

Information Disclosure Statement

Receipt of Information Disclosure Statements filed November 4, 2010 and April 6, 2011 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

possession of the claimed invention. Claim 14 is drawn to a method of enhancing mucus function comprising administering an effective amount of a mucothickening agent to a subject in need thereof, wherein the mucothickening agent is any agent that promotes the formation of one or more of the following in mucus: covalent bonds, ionic bonds, hydrogen bonds, van der Waals' forces, intermingling or extracellular DNA and F-actin network.

In view of University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886, (U.S. Court of Appeals Federal Circuit, 2004), the claim does not identify any compound or provide evidence that those skilled in the art could identify compounds based on the claim's vague functional description. At best, it simply indicates that one should run tests on a wide spectrum of compounds in the hope that at least one of the many possible compounds will provide the desired functional limitations of the formation of covalent bonds, ionic bonds, hydrogen bonds, van der Waals' forces, intermingling or extracellular DNA and F-actin network in mucus. The factors considered in the Written Description requirement are (1) *level of skill and knowledge in the art,* (2) *partial structure,* (3) *physical and/or chemical properties*, (4) *functional characteristics alone or coupled with a known or disclosed correlation between structure and function*, and the (5) *method of making the claimed invention.*

While all of the factors have been considered, only those required for a *prima facie* case are set forth below.

The specification discusses on page 6, paragraph 3, the mucothickening agent is any agent that promotes the formation of one or more of the following in mucus:

covalent bonds, ionic bonds, hydrogen bonds, van der Waals' forces, intermingling or extracellular DNA and F-actin network, which can be any number of agents.

The claim is drawn to a method of enhancing mucus function comprising administering an effective amount of a mucothickening agent to a subject in need thereof, wherein the mucothickening agent is any agent that promotes the formation of one or more of the following in mucus: covalent bonds, ionic bonds, hydrogen bonds, van der Waals' forces, intermingling or extracellular DNA and F-actin network.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is whatever is now claimed (see page 1117). A review of the language of the claims indicates that the claim is drawn to any agent that can form covalent bonds, ionic bonds, hydrogen bonds, van der Waals' forces, intermingling or extracellular DNA and F-actin network in mucus. There are only a few genus explicitly disclosed, see claim 15. The specification discloses specific species in examples 1-6, pages 22-27 and in claim 16.

The disclosure of the disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. The present claim encompasses any and all compounds that can form covalent bonds, ionic bonds, hydrogen bonds, van der Waals' forces, intermingling or extracellular DNA and F-actin network in mucus. There is substantial variability among the species of agents encompassed within the scope of the claim because the specific species in examples 1-

6 and claim 16 are only representative molecules amongst an entire class of molecules that can have widely differing structures and corresponding biological activities. Further, defining the composition in functional terms would not suffice in the absence of a disclosure of structural features or elements of the mucothickening agent that would have the stated function. Applicant is describing what the composition does rather than what it is. Describing a compound by its functions will not substitute for written description of the structure of the compound. The invention should be explained in such a way as to describe what the invention is, not what the invention does. Describing the function of a compound fails to distinguish the compound from other molecules or agents that can perform the same functions.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Consequently, the Examiner notes that the claimed invention which is drawn to a genus of agents may be adequately described if there is a (1) sufficient description of a representative number of species, or (2) by disclosure of relevant, identifying characteristics sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. Here, the specification does not disclose the common structural feature shared by the members of the claimed genus. Since the claimed genus encompasses agents yet to be discovered,

the disclosed undisclosed structural feature does not constitute a substantial portion of the claimed genus. Therefore, the disclosure of agents does not provide an adequate description of the claimed genus.

Weighing all the factors, the breadth of the claim reading on compositions yet to be discovered, the lack of correlation between structure and function of the compositions, level of knowledge and skill in the art, one of ordinary skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of agents that can form covalent bonds, ionic bonds, hydrogen bonds, van der Waals' forces, intermingling or extracellular DNA and F-actin network in mucus At best, it simply indicates that one should run tests on a wide spectrum of compounds in the hope that at least one of them will work. Neither the exemplary embodiments nor the specification's general method appears to describe structural features, in structural terms that are common to the genus. That is, the specification provides neither a representative number of agents to describe the claimed genus, nor does it provide a description of structural features that are common to the agents. In essence, the specification simply directs those skilled in the art to go figure out for themselves the structure of the claimed mucothickening agents.

The written description requirement is not satisfied.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 8, 15, and 16 are rejected for use of improper Markush language. Claims 2, line 2 states" function is selected from". The proper language should be "function is selected from the group consisting of". Claim 8, line 2, states "selected from". The proper language should be "selected from the group consisting of". Claim 15, line 2, states "agent is selected from". The proper language should be "agent is selected from the group consisting of". Claim 16, line 2, states "agent is selected from". The proper language should be "agent is selected from the group consisting of".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4, and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by the Feng Publication (1998) (Feng et al.).

Feng et al. disclose that most patients with cystic fibrosis (CF) are infected with *Pseudomonas aeruginosa*. Feng et al. disclose that dextran exhibits antiadhesive effects in preventing attachment of *P. aeruginosa* to epithelial cells (epithelial protection). Feng et al. disclose that the initial purpose of the study was to evaluate the potential of dextran to alter the rheology and ciliary transportability of CF sputum prior to initiation of a clinical trial in patients with CF. Feng et al. disclose that overall, whether for CF sputum or healthy dog mucus, Dextran 4000 treatment significantly reduced

viscoelasticity and increased predicted mucociliary and cough clearability (enhancing mucus function administering a mucothickening agent, dextran). Feng et al. further disclose that treatment with Dextran 4000 can reduce the crosslink density and cohesiveness of CF and improve mucociliary and cough clearability . Dextran 4000 is an inexpensive and nontoxic agent that may be of benefit in patients with CF lung disease and perhaps in other respiratory disease where mucus retention is an important feature (Abstract).

Feng et al. meet all the limitations of the claims and thereby anticipate the claims.

Claims 1-2, 4, and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by the King et al. (US 6,339,075).

King et al. disclose a method of improving mucus clearance comprising administering to the respiratory tract of a patient in need of such treatment an effective amount of a polysaccharide (col. 2, lines 57-60) (method of enhancing mucus function comprising administering an effective amount of a mucothickening agent, polysaccharide). King et al. disclose a method of improving mucus clearability in a patient having cystic fibrosis comprising administering to the respiratory tract of the patient in need of such treatment an effective amount of dextran (col. 2, lines 66-67-col. 3, lines 1-3) (dextrin, respiratory lining). King et al. disclose that the mechanism for the improvement in viscoelasticity with dextran administration is believed to be due to the substitution of dextran moieties in hydrogen bonding sites otherwise occupied by oligosaccharide moieties linked to neighboring high molecular weight peptides. The

original intermolecular mucin-mucin bonds contribute to the three-dimensional structure that makes up the mucus gel, while the new mucin-dextrin bonds form ineffective crosslinks because of the relatively small length of the dextran polymer (col. 4, lines 16-25).

King et al. meet all the limitations of the claims and thereby anticipate the claims.

Claims 1-2, 4, 7-9, and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by the Edwards et al. (CA 2,483,917).

Edwards et al. disclose that formulations have been developed for pulmonary delivery to treat or reduce the infectivity of diseases such as viral infections, especially tuberculosis, SARS, influenza, cytomegalovirus and RSV in humans and hoof and mouth disease in animals. Edwards et al. disclose the formulations for pulmonary administration include a material that significantly alters physical properties, such as surface tension, surface elasticity and bulk elasticity of lung mucus lining fluid, which may be a surfactant and optionally, a carrier. The formulation may be administered as a powder where the particles consist basically of the material altering surface properties, such as surface tension and/or surface and/or bulk elasticity. The carrier may be a solution, such as alcohol, or a material mixed with the material altering surface properties to form particles. Edwards et al. disclose these include polysaccharides such as dextran, which also has surface active properties (page 7, lines 5-16). Edwards et al. disclose the formulations are administered either as a powder or aerosol, preferably prior to or shortly after infection, to decrease or prevent infection and then viral

shedding. Edwards et al. disclose the formulation is administered in an amount sufficient to decrease surface instabilities in the liquid lining the airways of the lung, i.e., to damp the rate of droplet formation from lung fluid (page 7, lines 22-30). Edwards et al. disclose that an example shows using a suitable quantity and size of a macromolecule, such as 50 K Da dextran can also significantly reduce aerosolization (decreasing aerosolization).

Edwards et al. meet all the limitations of the claims and thereby anticipate the claims.

None of the claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andriae M. Holt whose telephone number is (571)272-9328. The examiner can normally be reached on 7:00 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richter Johann can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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